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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,025

10/30/2003

Carlos Schuler

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NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

DOUGLAS, STEVEN O

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

02/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,025	Applicant(s) SCHULER ET AL.	
	Examiner /Steven O. Douglas/	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 26-50 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 18-20, 26, 28, 31, 40, 42, 48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16, 17, 29, 30, 32-39, 41, 43-47 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (US Pat. 5,183,187) in view of Galia (US Pat. 4,433,797).

The Martin et al. reference discloses an aerosolization apparatus comprising a container 11 containing a pharmaceutical formulation a metering chamber (proximate reference numeral 31), a valve assembly 13 and a pressurizer 19 that is actuated by the increase in liquid pressure created by squeezing the container. Martin et al. fails to disclose first and second pressurizers as claimed. The Galia reference discloses another aerosolization apparatus that utilizes a first pressurizer (i.e. the propellant for the liquid being dispensed) to actuate a second pressurizer (i.e. the diaphragm 54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Martin et al. apparatus to have first and second pressurizers as claimed, wherein so doing would amount to the mere substitution of one pressurizing arrangement (i.e. one that is pressurized to actuate the metering chamber by manual squeezing) for another (i.e. one that is pressurized to actuate the metering chamber by the propellant contained in liquid to be dispensed). Furthermore, such substitution would have a reasonable amount of predictable success by one of ordinary skill in the art in the liquid dispensing arts.

Claims 1-13,16,17,32-39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al in view of Galia.

The Martin et al. reference discloses a medicament dispensing apparatus (supra), but does not disclose the metering chamber as being sized so at least 2 mg of active agent is aerosolized (claim 1 and 32), the metering chamber as being sized so at least 3 mg of active agent is aerosolized (claim 5 and 34), the metering chamber as being sized so at least 5 mg of active agent is aerosolized (claim 6 and 35), the metering chamber as being sized to contain at least 50 μm (claim 7), the metering chamber as being sized to contain at least 150 μm (claim 8), the metering chamber as being sized to contain at least 300 μm (claim 9), the pressurizer is arranged so that at least 50% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm (claim 10 and 36) or the pressurizer is arranged so that at least 80% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm (claim 11 and 37). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the metering chamber as being sized so at least 2 mg of active agent is aerosolized (claim 1 and 32), the metering chamber as being sized so at least 3 mg of active agent is aerosolized (claim 5 and 34), the metering chamber as being sized so at least 5 mg of active agent is aerosolized (claim 6 and 35), the metering chamber as being sized to contain at least 50 μm (claim 7), the metering chamber as being sized to contain at least 150 μm (claim 8), the metering chamber as being sized to contain at least 300 μm (claim 9), the pressurizer is arranged so that at least 50% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm (claim 10 and 36) or the pressurizer is arranged so that at least 80% of the aerosol particles generated have a diametric size of from 0.1 μm to 10 μm (claim 11 and 37), since it has been held that where the general

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conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regard to claims 32-39 and 41, the method as claimed would be inherent during the normal use and operation of resulting device.

Claims 29,30,43-47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. in view of Galia as applied to claims 1-13,16,17,21-25,27,32-39 and 41 and further in view of Riebe et al. (US Pat. 6,644,306).

The Martin et al. reference discloses a medicament dispensing apparatus (supra), but does not disclose an aerosolized agent as being insulin. The Riebe et al. reference discloses another medicament dispensing apparatus arranged for dispensing the active ingredient insulin in order to treat a patient for diabetes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Martin et al. device to dispense insulin in view of the teachings of the Riebe et al. reference to treat a patient for diabetes.

In regard to claims 43-47 and 49, the method as claimed would be inherent during the normal use and operation of device resulting from the combination of references.

Response to Arguments

Applicant's arguments with respect to claims 1-13,16,17,29,30,32-39,41,43-47 and 49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/
Primary Examiner
Art Unit 3771

SD
2/6/08